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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,219	01/12/2004	Donald R. Sandell	4696C1	1150

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MILA KASAN, PATENT DEPT.  
APPLIED BIOSYSTEMS  
850 LINCOLN CENTRE DRIVE  
FOSTER CITY, CA 94404

EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/756,219

**Applicant(s)**

SANDELL, DONALD R.

**Examiner**

William H. Beisner

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 36-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurz et al. (US 6,767,512 or WO 98/20975) in view of Woudenberg et al.(US 5,928,907) and Yamamoto et al.(US 5,102,623) or Pfoest et al.(US 5,496,517).

The reference of Lurz et al. discloses a thermal cycling device (4) that includes a sample block assembly (7,8,9,21,22,23,26) and a sample well tray holder (5) configured to hold a sample well tray. The sample block assembly is independently translatable.

While the reference of Lurz et al. discloses a fixed cover or platen (12) that is heated, the reference is silent as to the presence of an optical detection system that is required of independent claims 36, 43, 45 and 52.

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The reference of Woudenberg et al. discloses that it is known in the art to configure a cover or platen (14) that is heated within an integrated optical detection system (10, 8, 6, 4, 2) (See Figure 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the cover or platen (12) of the reference of Lurz et al. with an optical detection system as suggested by the reference of Woudenberg et al. for the known and expected result of providing a means recognized in the art for providing real-time fluorescence detection of the thermal cycling reaction within the sample wells.

Claims 36, 43, 45 and 52 further differ by reciting that the sample well tray holder (5) is independently translatable relative to the sample block assembly and positions a sample well tray into alignment with the sample block assembly and the optical detection system.

The reference of Yamamoto et al. discloses that it is known in the art to automate the introduction of liquid reagents into a sample well tray (14) using a sample well tray holder (11) that is independently translatable with respect to a sample block (26) at a sample heating station.

The reference of Pfost et al. discloses a device capable of thermal cycling that includes a sample block assembly(60); and a sample well tray holder (34) for holding a sample well tray (44). The sample block assembly and sample well tray holder are independently translatable to position a sample well tray in a position for temperature control of the sample well tray (See Figure 6).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of the modified primary reference so as to automate the introduction of the reagents into the sample well tray as

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suggested by the reference of Yamamoto et al. or Pfost et al. for the known and expected result of providing automation of the sample preparation steps prior to the thermal cycling process and/or while providing a stable environment for storing unstable enzyme reagents (See column 1, lines 45-55, of Yamamoto et al.).

Modification of the reference of Lurz et al. to include an optical detection system and translatable sample tray holder as suggested by the references of Woudenberg et al. and Yamamoto et al. would result in a device and method of use wherein the sample block assembly and sample well tray holder are independently translatable to position a sample well tray with nucleic acid amplification samples into alignment with the sample block assembly and the optical detection system.

With respect to claims 37, 44, 46 and 53, the optical detection system would remain stationary during the movement of a sample well tray within the device.

With respect to claims 38 and 47, the sample block assembly includes sample block (7, 8 or 9) for contacting the sample well tray.

With respect to claims 39 and 48, the device includes a positioning mechanism (22, 23, 26) configured to translate the sample block (7, 8, 9).

With respect to claims 40 and 49, the positioning mechanism includes a plurality of links (22).

With respect to claims 41 and 50, the positioning mechanism includes a motor (27) for moving the links.

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With respect to claims 45 and 52, translation of the sample well tray holder as suggested above would bring the optical detection system and nucleic amplification sample into direct optical alignment.

With respect to claim 51, the resulting device would be a real-time PCR machine.

#### ***Terminal Disclaimer***

4. The terminal disclaimer filed on 10/19/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,677,151 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Response to Arguments***

5. Applicant's arguments, see pages 6-8, filed 10/19/05, with respect to the rejection(s) of claim(s) 36 and 43 and the claims dependent therefrom under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the combination of the references of Lurz et al.(US 6,767,512 or WO 98/20975) in view of Woudenberg et al.(US 5,928,907) and Yamamoto et al.(US 5,102,623) or Pfoest et al.(US 5,496,517).


#### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB